

## REMARKS

In the Official Action dated July 1, 2003, claims 1-11 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enabling support. Claims 3 and 10-11 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. Claims 1, 3-7, 9 and 11 are rejected under 35 U.S.C. § 102(e) as allegedly anticipated by either U.S. Patent No. 6,294,538 (hereinafter "Mylari") or U.S. Patent No. 6,277,877 (hereinafter "Hoover"). Claims 1-3 have been further rejected under 35 U.S.C. § 103(a) as allegedly obvious over Hoover in view of Mylari.

This response addresses each of the Examiner's rejections. Accordingly, the present application is in condition for allowance. Favorable consideration of all pending claims is respectfully requested.

Claims 1-11 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement for prevention of injury to the myocardium or prevention of the onset of diabetic cardiomyopathy. Claims 1-11 have also been rejected as allegedly lacking enablement for making and using the prodrug and salts of claimed compounds, or for use of the prodrugs and/or salts thereof in conjunction with additional compounds including the analogs, antagonists and agonists of the claimed additional compounds.

In response and in an effort to expedite favorable prosecution, Applicant has amended claims 1-4 and 8-11. Support for the amendment can be found throughout the specification, e.g., at page 4, line 6-21. Applicant respectfully submits that the specification contains written description to enable any person skilled in the art to make and use the invention as claimed in the instant claims. The specification provides sufficient description for the treatment of diabetic cardiomyopathy at page 4, line 2 - page 6, line 6; page 6, line 27 - page 8, line 5; for prevention of injury to the myocardium at page 6, lines 7-22; for prevention of the onset of diabetic cardiomyopathy at page 6, lines 23-26; for prodrugs and salts of the prodrugs at page 45, line 19 – page 46, line 23; and for prodrugs and/or salts of the prodrugs in conjunction with additional compounds including the analogs at page 46, line 8 – page 61, line 19. Accordingly, Applicant submits that there is enabling written description in the specification for the instant

claims. Hence, Applicant respectfully requests the withdrawal of this rejection. No new matter has been added.

Claims 3 and 10-11 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. As indicated, Applicant has amended the claims to expedite favorable prosecution. No new matter has been added. Support for the amendments can be found throughout the specification, e.g., at page 58, line 19 for a full description of the acronym NHE. Accordingly, Applicant submits that the claims, as amended, overcome this rejection and respectfully requests the withdrawal of this rejection.

Claims 1, 3-7, 9 and 11 have been rejected under 35 U.S.C. § 102(e) as allegedly anticipated by U.S. Patent No. 6,294,538 (Mylari). To expedite favorable prosecution, Applicant has canceled claim 2 without prejudice and redrafted claims 1, 3 and 11. Support for the amendments can be found throughout the specification, e.g., at page 4, line 6-21. Mylari discloses sorbitol dehydrogenase inhibitory compounds and pharmaceutical compositions and methods of using sorbitol dehydrogenase inhibitory compounds in the treatment of diabetic complications, particularly diabetic neuropathy and diabetic cardiomyopathy. Mylari also discloses pharmaceutical compositions and kits of sorbitol dehydrogenase inhibitory compounds in combination with a glycogen phosphorylase inhibitor. However, Mylari does not teach the GPIs recited in the pending claims. Applicant respectfully submits that Mylari does not teach or disclose the subject matter of the claimed invention. Accordingly, Applicant submits that the claims, as amended, overcome this rejection and respectfully requests the withdrawal of the rejection.

Claims 1-8 have been rejected under 35 U.S.C. § 102(e) as allegedly anticipated by U.S. Patent No. 6,277,877 (Hoover). Claims 1, 3-7, 9 and 11 have been further rejected under 35 U.S.C. § 102(e) as allegedly anticipated by either Mylari or by Hoover. To expedite favorable prosecution, Applicant has canceled claim 2 without prejudice and redrafted claims 1, 3, 4 and 8. Support for the amendment can be found throughout the specification, e.g., at page 4, line 6-21. Hoover does not teach the GPIs recited in the instant claims. Hoover teaches treatment of diabetes and hypertension only, but not diabetic cardiomyopathy, a characteristically distinct disorder. Therefore,

Applicant respectfully submits that Hoover does not teach or disclose the subject matter of the claimed invention. Accordingly, Applicant submits that the claims, as amended, overcome this rejection and respectfully requests the withdrawal of the rejection.

Claims 1-3 have been further rejected under 35 U.S.C. § 103(a) as allegedly obvious over Hoover in view of Mylari. As explained above, to expedite favorable prosecution, Applicant has amended the claims and submits that neither Hoover or Mylari teach or suggest or provide motivation to a person of ordinary skill in the art at the time of the invention to use any of the GPIs recited in the instant claims.

The Examiner acknowledges that Hoover does not teach the use of the compounds of the instant claims in the treatment of diabetic cardiomyopathy. In addition, contrary to the Examiner's contention, Hoover does not disclose any of the GPIs claimed in the present invention.

Mylari discloses a pharmaceutical composition comprising a sorbitol dehydrogenase inhibitor and a glycogen phosphorylase inhibitor, known for treating diabetes. However, contrary to the Examiner's contention, Mylari does not disclose any treatment of diabetic patients having diabetic cardiomyopathy using any GPI alone. Mylari teaches the use of GPIs in combination with sorbitol dehydrogenase inhibitors for the treatment of diabetic cardiomyopathy. Thus, according to Mylari, a GPI has to be used along with sorbitol dehydrogenase inhibitor. Nowhere in Mylari is there a suggestion or recognition that a GPI alone may be used for the treatment of diabetic cardiomyopathy. Further, the Examiner acknowledges that Mylari does not teach the GPI compounds of the claimed invention.

Accordingly, Hoover or Mylari, either alone or in combination, does not suggest a method of treating diabetic cardiomyopathy using any of the GPIs alone or provide motivation to the skilled in the art to attain a method of treatment of cardiomyopathy as recited in the present claims. Therefore, it would be unobvious to a person of ordinary skill in the art, at the time of the invention was made, to use a method of treating diabetic cardiomyopathy using any of the GPIs alone as claimed in the present invention. Applicant submits that this rejection is unsupported by the cited art and respectfully requests the withdrawal of the rejection.

Thus, in view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance. Accordingly, it is respectfully requested that this application be allowed and a notice of allowance be issued.

Respectfully submitted,



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